

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

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03 JAN 2010

FILE No.

43838

G.E. EHRLICH (1995) LTD.

Date of mailing (day/month/year)

23 December 2009 (23.12.2009)

Applicant's or agent's file reference

43838

IMPORTANT NOTICE

International application No.

PCT/IL2008/000786

International filing date (day/month/year)

11 June 2008 (11.06.2008)

Priority date (day/month/year)

11 June 2007 (11.06.2007)

Applicant

CONTIPI LTD. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 43838	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IL2008/000786	International filing date (<i>day/month/year</i>) 11 June 2008 (11.06.2008)	Priority date (<i>day/month/year</i>) 11 June 2007 (11.06.2007)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant CONTIPI LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 11 December 2009 (11.12.2009)</p> <p>Authorized officer</p> <p style="text-align: center; font-size: 1.2em;">Simin Baharlou</p> <p>e-mail: pt09.pct@wipo.int</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/L2008/000786

International filing date (day/month/year)
11.06.2008

Priority date (day/month/year)
11.06.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/00

Applicant
CONTIPI LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

See form
PCT/ISA/210

Authorized Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2008/000786

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2008/000786

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 29-52

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 29-52

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13~~ter~~.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/L2008/000786

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>3, 5-19</u>
	No: Claims	<u>1, 2, 4, 20-28</u>
Inventive step (IS)	Yes: Claims	<u>3, 5-7, 14-18</u>
	No: Claims	<u>1, 2, 4, 8-13, 19-28</u>
Industrial applicability (IA)	Yes: Claims	<u>1-28</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Independent claims 29 and 52 refer to a method for ameliorating female incontinence which is a therapeutical method (Rule 39.1 (iv) PCT during the search phase and Rule 67.1 (iv) PCT during the examination phase). In addition, as the device is inserted in the private sphere, it is excluded from industrial applicability, Articles 33(1), (4) PCT. Claims 30 - 51 being dependent on claim 29 equally do not fulfill the above requirements of the PCT.

Re Item V.

1 Reference is made to the following documents:

D1: DE 198 16 349 A1 (HUEBNER FRANK-PETER [DE]) 14 October 1999 (1999-10-14)

D2: WO 2005/087153 A (CONTIPI LTD [IL]; ZIV ELAN [IL]) 22 September 2005 (2005-09-22)

D3: DE 271 657 C (LEVY) 17 March 1914 (1914-03-17)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document: col. 1, line 56 - col. 2, line 40, figures):

An apparatus for amelioration of urinary incontinence in a female subject (col. 1, lines 3-5), the apparatus comprising:

(a) a ring (2) with adjustable stiffness (see comment 1), adapted for intra-vaginal insertion; and

(b) a stabilizing projection (1), extending transversely to a plane of said stiffenable ring (2), said stabilizing projection having a size, shape, stiffness and position configured to

stabilize said stiffenable ring within the vagina.

Comment 1:

The ring 2 is inflatably dependent on the use thereof, i.e. the stiffness of the ring can be adjusted to its needs, see column 2, lines 10 - 24 and especially the wording "Durch die **bedarfsgerecht** zunehmende Füllung des Ringpessars kann der Hebe- und Unterstützungseffekt des Silikonschalenpessars vergrößert werden...".

3 DEPENDENT CLAIMS 2, 4, 8 - 13, 19 - 28

3.1 Dependent claims 2, 4, 8-13, 20 - 28 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see documents D1 and D2 and their citations in the search report.

3.2 In claim 19 a slight constructional change in the design of the stabilizing extension of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 19 also lacks an inventive step.

4 DEPENDENT CLAIMS 3, 5 - 7, 14 - 18

The combination of the features of dependent claims 3, 5-7, 13-20, 26 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

4.1 In document D1 a ring (2) is inflatable with gas or liquid. Said stiffenable ring is therefore adapted to switch from a first geometric configuration outside the body (the ring is not inflated) to a second configuration after intra vaginal insertion (the ring can be fully inflated) and as such D1 comprises all the technical features of claim 2.

Claim 3 being dependent on claim 2 claims that said switch from said first configuration to

said second configuration is performed mechanically. This is not disclosed in D1 and as such claim 3 fulfills the requirement of novelty, Article 33(2) PCT.

The problem to be solved by a mechanical switch is to avoid any leakage problems that could arise with inflatable systems.

No other switch is suggested in D1 and although a mechanical switch is disclosed in document D3 (spring 8), both documents cannot be combined as their construction is completely different. Furthermore, due to the umbrella mechanism in D3, there are only two positions possible: closed and open and the opening diameter of the umbrella cannot be adjusted.

Therefore, the subject-matter of claim 1 involves an inventive step and meets the requirements of Article 33(3) PCT.

Claims 4 - 28 being dependent on claims 1 - 3 specify advantageous embodiments of the subject-matter of claims 1 - 3 and fulfill the requirements of Articles 33(2), (3) and (4) PCT as well.

4.2 Equally, **claim 5** being dependent on claims 1 and 4 fulfills the requirements of novelty and inventive step as briefly explained below:

Document D2 discloses (see page 16, line 4 - page 17, line 16; figures 10A - 11) an apparatus (1000) including a tensioning extension (1106) adapted to extend outside of the body, said tensioning extension (1106) adapted for selectively increasing and decreasing a rigidity of said ring after insertion thereof.

The tensioning extension of D2 solves the same problem as in D1, namely how to inflate the ring and is only an alternative to the pump inflation as disclosed in D1. As such claim 3 is not inventive in view of D1 and D2.

The subject-matter of claim 5 differs from this state of the art (D2) in that said apparatus

includes a stiffening control.

In view of said difference the subject-matter of claims 4 and 5 is new and meets the requirements of Article 33(2) PCT.

The problem to be solved by a stiffening control is to suit the needs of individual conditions.

None of the prior art documents cited in the search report disclose any control mechanisms for intermediate steps to stiffen a ring.

Therefore, the subject-matter of claim 5 involves an inventive step and meets the requirements of Article 33(3) PCT.

Claims 5 - 28 being dependent on claims 1 and 4 specify advantageous embodiments of the subject-matter of claims 1 and 4 and fulfill the requirements of Articles 33(2), (3) and (4) PCT as well.

